REMARKS

Claims 47-55, 57, and 58-73 are pending, with claims 48 and 51 withdrawn pending the allowance of a generic or a linking claim. Claim 53 is allowed. By this Amendment, claims 20-27 and 56 are cancelled and new claims 58-73 are added. Claims 47, 54 and 57 are amended. The specification supports the amendment to claim 47 with regard to the controlled release agent can be found for example on page 8, lines 2-3 of the original application. The specification supports the amendment to claim 54 can be found for example on page 9, lines 4-5 and on page 17, lines 14-16 of the original application. The specification supports the amendment to claim 57 with regard to the polymer matrix can be found for example on page 24, lines 22-25 of the original application.

Support for new claims 58, 65, and 70 can be found for example on page 21, lines 22-25 of the original application. Support for new claims 59, 60, 66, 67, 71, and 72 can be found for example from page 21, line 26 to page 22, line 23 of the original application. Support for new claims 61, 68, and 73 can be found for example on page 23, lines 1-10 of the original application. Support for new claim 62 can be found for example from the original claim 25. Support for new claims 63 and 69 can be found for example from the original claim 26. Support for new claim 64 can be found for example from the original claim 27. No new matter is introduced.

Allowable Subject Matter

The Examiner indicated claim 53 is allowed and claims 22, 23, 27 are allowable. Claims 22, 23, and 27 are rewritten as claims 59, 60, and 64 respectively to be dependent of the allowed claim 53, along with new dependent claims 58 and 61-63. Because claims 58-64 are dependent of the now allowed claim 53, claims 58-64 are also allowable. Confirmation of the allowance of claims 58-64 are respectfully requested.

Objection to the Specification

Claim 20 is cancelled. In view of the cancellation of claim 20, objection of specification related to claim 20 is moot. Withdrawal of the objection is respectfully requested.

The Examiner asserted that the specification failed to disclose the claimed device. Claim 47 is amended for clarification to indicate the surface capillary fibers are associated with a portion of the device to be placed within the patient. Amendment of claim 47 obviates the objection. Withdrawal of the objection is respectfully requested.

Objection to the Claims

Claims 20-27, 47, 49, 50, 52, and 54-56 are objected to because of informalities related to the phrase "surface capillaries associated with a portion of the device." Claims 20-27 and 56 are cancelled. In view of the cancellation of the claims, objection to claims 20-27 and 56 is moot. Claim 54 has been amended to depend from the allowed claim 53. Amendment of claim 54 obviates the rejection. Claims 49, 50, 52, and 55 are dependent of claim 47. Claim 47 is amended to indicate the surface capillary fibers are associated with a portion of the device to be placed within the patient. Amendment of claim 47 obviates the objection to claims 47, 49, 50, 52, and 55 since the language noted by the Examiner has been clarified. Withdrawal of the objection is respectfully requested.

35 U.S.C. §103(a) Rejections

I. Claims 20, 25, 26, 47, 54, 55, and 57 are rejected as being unpatentable over Vaughn et al ("Expanded Surface Area Fibers: A Means for Medical Product Enhancement") in view of Deker (U.S. Patent No. 2,972,350).

Claims 20, 25, and 26 are cancelled. In view of the cancellation of the claims, rejection to claims 20, 25, and 26 is moot. Withdrawal of the rejection of these claims is respectfully

requested. Claim 54 is amended to be dependent of the now allowed claim 53. Amendment of claim 54 obviates the rejection. Withdrawal of the rejection to claim 54 is respectfully requested.

"In rejecting claims under 35 U.S.C. §103, the examiner bears the initial burden of presenting a prima facie case of obviousness." In re Rijckaert, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). Prima facie obviousness is not established if all the elements of the rejected claim are not disclosed or suggested in the cited art. In re Ochiai, 37 USPQ 1127, 1131 (Fed. Cir. 1995). "The test for obviousness *vel non* is statutory. It requires that one compare the claim's 'subject matter as a whole' with the prior art 'to which said subject matter pertains.'"). "It is impermissible, however, to simply engage in a hindsight reconstruction of the claimed invention, using applicant's structure as a template and selecting elements from references to fill the gaps." In re Gorman, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991)(emphasis added).

Claims 47 and 55

Claims 55 is dependent of claim 47. Claim 47 is amended to indicate the bioactive agent is associated with a controlled release agent. The amendment to claim 47 with regard to the controlled release agent is for the purpose of facilitating prosecution only. Vaughn and Deker alone or combined does not teach or suggest each and every element of amended claim 47 and its dependent claim 55.

Vaughn does not teach or suggest using the surface capillary fibers (SCFs) in percutaneous or implantable applications. The list of applications that might benefit through the use of SCFs listed in Fig. 10 appears to be directed to external applications. Although Vaughn discloses vaguely of release material from the grooves of SCFs over a period of time, there is no teaching or suggestion from Vaughn of the use of a controlled release agent.

Deker is directed to ways to make surgical sponges that are intended primarily as absorbent material (see independent claims 1, 8, 12, and 16 of Deker). Deker vaguely teaches

using the surgical sponge to apply medication in a surgical setting, which is presumably applied for immediate release of the medication. Similar to Vaughn, Deker does not teach or suggest applying medication specifically in percutaneous or implantable applications either. Vaughn in view of Deker therefore does not teach or suggest using the sponge in percutaneous or implantable applications and the bioactive agent is eluted in a controlled way upon contacting the fluids/tissue and the bioactive agent is associated with a controlled release agent.

In contrast, claim 47 is a method claim that clearly indicated the device used is for percutaneous or implantable applications. The bioactive agent is eluted in a controlled way upon contacting the fluids/tissue and the bioactive agent is associated with a controlled release agent. Vaughn in view of Deker therefore clearly does not teach or suggest each and every element of the claim 47. Vaughn in view of Deker does not render the claim 47 *prima facie* obvious. While Applicants do not acquiesce in the assertions regarding the dependent claims, these issues are not discussed further in view of the discussion of claim 47 that makes the issue of the dependent claims presently moot. Withdrawal of the rejection is respectively requested.

Claim 57

Claim 57 is directed to bioactive agent **pre-loaded** within the **polymer matrix** of the SCFs, which means the bioactive agent is part of the SCFs, not just filling the grooves or capillaries of the fibers. Vaughn is completely silent with integrating or incorporating bioactive agent into the polymer of the fiber itself. For all the places cited by the Examiner of Vaughn, Vaughn only discloses filling the grooves or capillaries of the fibers, not the actual integration or incorporation of the bioactive agent into the polymer of the fibers itself. Additionally, as discussed above, Vaughn does not teach or suggest using the sponge in percutaneous or implantable applications and the bioactive agent is eluted in a controlled way from the fibers upon contacting the fluids/tissue.

Deker also does not teach or suggest applying medication specifically in percutaneous or implantable applications. Furthermore, Deker is completely silent with bioactive agent being integrated or incorporated into the polymer of the sponge itself. Additionally, Deker does not teach or suggest the bioactive agent elutes in a controlled way from the fibers upon contacting the fluids/tissue. Vaughn in view of Deker therefore does not teach or suggest using the sponge in percutaneous or implantable applications and the bioactive agent is integrated or incorporated into the polymer of the device and elutes in a controlled way upon contacting the fluids/tissue.

Vaughn in view of Deker therefore clearly does not teach or suggest each and every element of claim 57. Vaughn in view of Deker does not render claim 57 *prima facie* obvious. Claim 57 is allowable. Withdrawal of the rejection is respectively requested.

II. Claims 21 and 24 are rejected as being unpatentable over Vaughn et al. in view of Deker and further in view of Lorenz et al. (U.S. Patent No. 5,156,601). Similar to Vaughn and Deker, Lorenz does not teach or suggest percutaneous or implantable applications, although claims 21 and 24 are cancelled and the rejection is moot in view of the cancellation of claims 21 and 24. Withdrawal of the rejection is respectfully requested.

III. Claims 21, 24, and 52 are rejected as being unpatentable over Vaughn et al. in view of Deker and further in view of Rothwell et al. (U.S. Patent Application Publication No. 2003/0040692). Claims 21 and 24 are cancelled and the rejection to claims 21 and 24 is moot in view of the cancellation of claims 21 and 24. Withdrawal of the rejection is respectfully requested.

Claim 52 depends from claim 47. With regard to claim 52, similar to Vaughn and Deker, Rothwell does not teach or suggest percutaneous or implantable applications. Additionally, Rothwell is directed to device to stop bleeding. Rothwell therefore, similar to Vaughn and Deker

does not teach or suggest bioactive agent elutes in controlled manner upon contacting fluids/tissue. Vaughn in view of Deker and further in view of Rothwell therefore clearly does not teach or suggest each and every element of claim 52. Vaughn in view of Deker further in view of Rothwell does not render claim 52 *prima facie* obvious. Claim 52 is allowable. Withdrawal of the rejection is respectively requested.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

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